

BenchMark Special Stains Wash II

REF

860-041

08309817001

IVD

INTENDED USE

The BenchMark Special Stains Wash II is intended for laboratory use to produce optimized staining results for use with the Special Stains reagents and staining kits. When diluted and prepared according to instructions, this solution provides a stable aqueous environment for qualitative histological stain in sections of formalin-fixed, paraffin-embedded (FFPE) tissue stained on a BenchMark Special Stains instrument.

This product is intended for in vitro diagnostic (IVD) use.

PRINCIPLE OF THE PROCEDURE

BenchMark Special Stains Wash II, when prepared according to instructions, produces an optimized Wash solution used with BenchMark Special Stains reagent kits, ancillary reagents and BenchMark Special Stains instrument to achieve the appropriate histochemistry staining. The instrument applies the appropriate amount of BenchMark Special Stains Wash II solution when required during each staining procedure.

MATERIAL PROVIDED

One bottle containing 40 mL of BenchMark Special Stains Wash II Surfactant; contains Tween 20.

One bottle containing 10 mL of BenchMark Special Stains Wash II Biocide; contains Bronopol and MIT (ProClin 950).

Reconstitution, Mixing, Dilution, Titration

BenchMark Special Stains Wash II must be diluted with deionized water prior to use, as follows:

1. Ensure the 20 L graduated carboy and Wash bulk bottle are clean to avoid microbial contamination. (Refer to the BenchMark Special Stains instrument User Guide for instructions.)
2. Check the spigot of the carboy to ensure it is in the off position.
3. Add 20 L deionized water to the 20 L graduated carboy. Note that water used in the dilution of the BenchMark Special Stains Wash II must meet Clinical Laboratory Standards Institute's (CLSI) specification for Clinical Laboratory Reagent Water. See CLSI Guideline C3-A4.
4. Place the 20 L carboy on a magnetic stir plate and add a magnetic stir bar into the carboy. Please refer to the Materials Required But Not Provided section for further details.
5. Turn the stir plate on to a medium-low mixing speed (≥ 300 RPM) without displacing the stir bar.
6. Handle the BenchMark Special Stains Wash II solution using proper personal protective equipment (PPE).
7. Empty the contents of the BenchMark Special Stains Wash II Surfactant bottle into the 20 L carboy over a period of 30 seconds.
8. Empty the contents of the BenchMark Special Stains Wash II Biocide bottle into the 20 L carboy over a period of 5 seconds.
9. Mix the 20 L carboy contents by continuing to stir for at least 10 minutes after addition of the BenchMark Special Stains Wash II Surfactant and BenchMark Special Stains Wash II Biocide.
10. Screw the cap on the carboy.
11. Loosen the cap slightly to prevent an airtight seal, ensuring the solution can flow properly from the spigot.

MATERIALS REQUIRED BUT NOT PROVIDED

Additional reagents including but not limited to BenchMark Special Stains reagent kits and ancillary components are not provided.

Not all products listed in the method sheet may be available in all geographies. Consult your local support representative.

The following reagents and materials may be required for staining but are not provided:

1. Deionized water
2. Magnetic stir plate, minimum 25 cm x 25 cm in size, able to support a maximum of 20 kg
3. Magnetic stir bar, 76 mm long and 12 mm diameter
4. General purpose laboratory equipment
5. BenchMark Special Stains instrument

STORAGE AND STABILITY

Upon receipt and when not in use, store at 15-30°C. Keep out of direct sunlight. Do not freeze.

This reagent is expiration dated. When properly stored, the reagent is stable to the date indicated on the label. Do not use reagent beyond the expiration date.

Diluted BenchMark Special Stains Wash II Solution

Store at 15-30°C. Keep out of direct sunlight.

Prepared as directed, testing has shown the diluted BenchMark Special Stains Wash II solution is stable for up to three months in the carboy or to the expiration date indicated in the original package label, whichever happens first.

Once diluted, the BenchMark Special Stains Wash II solution must be examined for microbial contamination prior to use. The signs indicating contamination or possible instability of this product are turbidity of the solution, odor development, or precipitation. At the first sign of possible reagent contamination or instability, contact your local support representative.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic (IVD) use.
2. For professional use only.
3. Take reasonable precautions when handling reagents. Avoid contact of reagents with eyes, skin, and mucous membranes. Use protective clothing and eyewear, and gloves.
4. ProClin 950 solution is used as a preservative in this solution. It is classified as an irritant and may cause sensitization through skin contact or inhalation. Take reasonable precautions when handling. Avoid contact of reagents with eyes, skin, and mucous membranes. Use protective clothing and gloves.
5. Materials of human or animal origin should be handled as biohazardous materials and disposed of with proper precautions. In the event of exposure, the health directives of the responsible authorities should be followed.^{1,2}
6. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
7. Avoid microbial contamination of product as it may cause incorrect results.
8. For further information on the use of this device, refer to the BenchMark Special Stains instrument User Guide, and instructions for use of all necessary components located at dialog.roche.com.
9. Consult local and/or state authorities with regard to recommended method of disposal.
10. Product safety labeling primarily follows EU GHS guidance. Safety data sheet available for professional user on request.
11. To report suspected serious incidents related to this device, contact the local Roche representative and the competent authority of the Member State or Country in which the user is established.
12. In order to ensure effective use, a well-mixed solution is required. Please refer to the Reconstitution, Mixing, Dilution, Titration section for further instructions.

This product contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Table 1. Hazard Information.

Hazard	Code	Statement
Danger	H315	Causes skin irritation.

Hazard	Code	Statement
	H317	May cause an allergic skin reaction.
	H319	Causes serious eye irritation.
	H331	Toxic if inhaled.
	H410	Very toxic to aquatic life with long lasting effects.
	P261	Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
	P264	Wash skin thoroughly after handling.
	P273	Avoid release to the environment.
	P280	Wear protective gloves/ eye protection/ face protection.
	P391	Collect spillage.
	P403 + P233	Store in a well-ventilated place. Keep container tightly closed.

INSTRUCTIONS FOR USE

The diluted BenchMark Special Stains Wash II solution is poured directly into the appropriate bulk fluid bottle of the AFM on the BenchMark Special Stains instrument. The diluted BenchMark Special Stains Wash II solution is applied automatically as required for the procedure being run.

Reagents have been developed for use on BenchMark Special Stains instrument in combination with BenchMark Special Stains reagents and accessories. The parameters for the automated procedures can be displayed, printed, and edited according to the procedure in the instrument User Guide. Other operating parameters for the instrument have been preset at the factory.

Refer to the appropriate staining kit method sheet for the recommended staining protocol and to the instrument User Guide for detailed instructions and additional protocol options.

PERFORMANCE CHARACTERISTICS

ANALYTICAL PERFORMANCE

BenchMark Special Stains Wash II solution provides a stable aqueous environment for qualitative histological stain in sections of FFPE tissue stained on a BenchMark Special Stains instrument. BenchMark Special Stains Wash II was tested at various incubation times with specific tissue types.

LIMITATIONS

BenchMark Special Stains Wash II has been optimally formulated for use on BenchMark Special Stains instruments.

Use only one Wash AFM bulk bottle on the instrument.

Once diluted, the solution should be examined prior to use for signs indicating contamination or possible instability of the product including turbidity, development of an odor, or presence of precipitate in the solution. At the first sign of possible reagent contamination or instability, contact your local support representative.

TROUBLESHOOTING

For corrective action, refer to the instrument User Guide or contact your local support representative.

- The BenchMark Special Stains Wash II Surfactant solution is heavier than water and will fall to the bottom of the carboy when added. Mix adequately using appropriate stir bar, stir plate and speed to ensure a homogenous solution is prepared.
- Once diluted, the pH of the wash solution should be above 4.5. Dispose of wash if pH falls below 4.5.

REFERENCES

- Occupational Safety and Health Standards: Occupational exposure to hazardous chemicals in laboratories. (29 CFR Part 1910.1450). Fed. Register.

- Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

NOTE: A point (period/stop) is always used in this document as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Ventana uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog. Roche.com for definition of symbols used):



Global Trade Item Number



Unique Device Identifier



Indicates the entity importing the medical device into the European Union

INTELLECTUAL PROPERTY

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